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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,810	09/20/2005	Vernon L. Alvarez	051530-5008-US	9490

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,810	ALVAREZ ET AL.	
	Examiner	Art Unit	
	DAVID LUKTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 3/13/08, no claim has been added, cancelled, or amended. Claims 42-49 remain pending.

Applicants' election of Group 14 is acknowledged, i.e., a method of altering the course of a biochemical process (or any method that is properly subgeneric thereto), and with the proviso that methods of treating diseases are excluded, and with the further proviso that diagnostic methods are excluded.

However, applicants have declined to elect species, as required by the previous Office action. In any case, a further restriction is now imposed.

. . . .

In addition to the foregoing, there is an error in the sequence listing. SEQ ID NO: 13 is the following: TTXXXMXXK. In the sequence listing, it is stated that "X" at position 3 must be Asn or Glu; by contrast, claim 42 recites that X1 must be Asp or Glu. It appears likely that the second of these two is intended, i.e., that the language of claim 42 controls, rather than the language of the sequence listing. Nonetheless, subgenera G5 and G6 have been created in order to get a statement from applicants on the record. (If the description of SEQ ID NO: 13 in the sequence listing is indeed incorrect, a new sequence listing will be required). Applicants should also note that there are at least two other discrepancies between the definition of the "X" variables in claim 42, and the description of the "X" variables in SEQ ID NO: 13.

A restriction requirement is now imposed. First, however, the following subgenera are defined (subgenera G1-G4 are the same as defined previously):

G1: This subgenus is limited to a method of altering the course of a biochemical process, either *in vivo* or *in vitro*; included would be a method of inhibiting proliferation of tumor cells;

G2: this subgenus is limited to a method of treating a disease in a host or otherwise improving the health of the host; treatment of cancer would be included in this subgenus;

G3: this subgenus is limited to diagnostic assays, such as (i) determining the extent to which a peptide, or series of peptides can alter the course of a biochemical process or (ii) determining the extent to which a peptide or series of peptides can bind to another physical entity;

G4: This subgenus includes any embodiment encompassed by claim 42, with the proviso the G1, G2 and G3 are excluded.

G5: in the elected method, substituent variable X1 is limited to aspartic acid or glutamic acid, in accordance with the claims filed 1/24/08;

G6: in the elected method, substituent variable X1 is limited to asparagine or glutamic acid, in accordance with what is defined in the sequence listing for SEQ ID NO: 13.

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. .§121 (the numbering begins with 18, in order to avoid conflict with the previous numbering system):

18) Claims 42-47, limited to G1.

19) Claim 48, limited to G1.

20) Claim 49, limited to G1.

The claimed inventions are distinct.

Groups {19, 20} and 18 are related as combination and subcombination, or alternatively Groups 18 and {19, 20} as related as mutually exclusive species in intermediate-final product relationship. Following are the form paragraphs for these situations:

> Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed.
>
> . . . .
>
> Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentable distict (MPEP section 806.04(h)).

Notwithstanding the foregoing, it is not unlikely that if both of the following conditions are met, there would be many embodiments within Groups 19 and 20 that would be novel: (a) Group 18 is determined to be novel, and (b) specific limitations were imposed on the nature of the cytotoxic agent, and more importantly the labeling group. Thus, in the event that Group 18 were determined to be novel, and specific limitations were imposed on the structure of the cytotoxic agent, and the structure of the labeling group, it would become appropriate to revisit the matter of restriction.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect species/ subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable (the lettering begins with "d"):

d) a specific cell type (with which the polypeptide is to be contacted in the elected method);

e) a specific biochemical process, the course of which is to be altered;

f) one of the following: G5 or G6;

g) one of the following: (i) in the elected method, the polypeptide is contacted with the cells *in vitro*, or (ii) the polypeptide is contacted with the cells *in vivo*;

h) in the event that the polypeptide is contacted with the cells *in vivo* (in the elected method), election is required of a specific route of administration (e.g., intravenous);

i) a specific and fully defined polypeptide in which all amino acids are accounted for and all other substituents (if any).

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. ∋103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654